



## BioLineRx Announces Expansion of Immuno-Oncology Collaboration in Pancreatic Cancer

July 30, 2018

**30-50 patients in additional arm will be investigated under the collaboration  
Results from combination of BL-8040 and KEYTRUDA® (pembrolizumab) in COMBAT/KEYNOTE-202 study will be reported in H2 2018 as planned**

TEL AVIV, Israel, July 30, 2018 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today the expansion of its immuno-oncology collaboration with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada) for the support of a Phase 2a program investigating BioLineRx's BL-8040 in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA, in patients with metastatic pancreatic cancer. Under the expansion, a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy will be added to the ongoing COMBAT/KEYNOTE-202 study. The triple combination arm will focus on second-line pancreatic cancer patients. Regulatory submissions required to conduct the additional arm of the study have been made and the trial is planned to be initiated in the fourth quarter of 2018.

BioLineRx previously disclosed partial results from the BL-8040 monotherapy portion of the COMBAT/KEYNOTE-202 study at the ASCO 2018 Gastrointestinal Cancers Symposium in January 2018. The partial monotherapy results showed that BL-8040 is safe and well tolerated and that BL-8040 increases infiltration of T cells into the tumor in patients with metastatic pancreatic cancer, confirming the mechanism of action of BL-8040 in this difficult-to-treat patient population. In addition, BL-8040 also induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood regulatory T cells (Tregs), known to impede the anti-tumor immune response, was decreased. Topline clinical results of the combination will be reported in H2 2018 as planned.

"We are very excited to report the expansion of our immuno-oncology collaboration with Merck and the inclusion of an additional arm in the COMBAT/KEYNOTE-202 study. The decision to investigate the combination of BL-8040 and KEYTRUDA, together with chemotherapy, stems from the encouraging results we have seen in the trial," stated Philip Serlin, Chief Executive Officer of BioLineRx. "These results continue to demonstrate the safety and tolerability of BL-8040, as well as validate its mechanism of action, namely that BL-8040 mobilizes immune cells into the peripheral blood, promotes T-cell infiltration into tumors, and has an effect on immuno-suppressive cells."

"In light of this," continued Mr. Serlin, "the addition of cytotoxic chemotherapy may be synergistic with the existing combination, due to the fact that besides helping to reduce the overall tumor burden, chemotherapy induces immunogenic cell death, thus leading to activation and expansion of new tumor-reactive T cells. Based on its demonstrated mechanism of action, BL-8040 should facilitate the infiltration of these T cells into the tumor core, alongside the restoration of T-cell activity within the tumor by KEYTRUDA. We look forward to presenting results from the dual combination arm of BL-8040 and KEYTRUDA in the COMBAT/KEYNOTE-202 study later this year, and expect to present results from the new triple combination arm of the study in the second half of next year."

### About the COMBAT/KEYNOTE-202 Study

The COMBAT/KEYNOTE-202 study, a Phase 2a study, is currently an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of the combination of BL-8040 and KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in over 30 subjects with metastatic pancreatic adenocarcinoma. The study is primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies, and is being carried out in the US, Israel and additional territories. The study is being conducted by BioLineRx under a collaboration agreement signed in 2016 between BioLineRx and MSD, through a subsidiary, to support a Phase 2a program investigating BioLineRx's BL-8040 in combination with KEYTRUDA in patients with metastatic pancreatic cancer.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells to peripheral blood and to be effective at inducing direct tumor cell death. In addition, clinical findings have demonstrated the ability of BL-8040 to mediate infiltration of T cells into tumors that were previously immunologically "cold" and devoid of immune cell infiltrate. Immune checkpoint inhibitors (such as KEYTRUDA) produce anti-cancer effects by increasing the activity of T cells through blockade of the interaction between the immune checkpoint receptor PD-1, on T cells, and its ligand PD-L1, on tumor cells. Pancreatic cancers have very little T-cell infiltrate, making them less susceptible to checkpoint blockade than other tumors that are infiltrated by T cells. Therefore, combining BL-8040 with immune checkpoint blockade is predicted to increase the responsiveness of pancreatic cancer patients to immunotherapy. Further increase in the sensitivity of pancreatic cancer cells to BL-8040 and KEYTRUDA may be achieved by chemotherapy-mediated immunogenic cell death and exposure of new tumor antigens resulting in activation of new anti-cancer T cell clones.

### About BL-8040

BL-8040 is a short synthetic peptide for the treatment of hematological malignancies, solid tumors, and stem cell mobilization. It functions as a high-affinity best-in-class antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells and immune-cells from the bone marrow, thereby sensitizing cancer cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing cell death (apoptosis). BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

### About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds,

develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is expected to initiate a first-in-human study in mid-2018. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the US and Canada), on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

For additional information on BioLineRx, please visit the Company's website at [www.bioglinerx.com](http://www.bioglinerx.com), where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).

*Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 6, 2018. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.*

**Contact:**

PCG Advisory  
Vivian Cervantes  
Investor Relations  
+1-646-863-6274  
[vivian@pcgadvisory.com](mailto:vivian@pcgadvisory.com)

or

Tsipi Haitovsky  
Public Relations  
+972-52-598-9892  
[tsipihai5@gmail.com](mailto:tsipihai5@gmail.com)

 View original content: <http://www.prnewswire.com/news-releases/bioglinerx-announces-expansion-of-immuno-oncology-collaboration-in-pancreatic-cancer-300688287.html>

SOURCE BioLineRx Ltd.